

**Research and evaluation of stability data of drug products in agreement
with Armenian drug law-regulations**

Varduhi M. Ghazoyan PhD *, Hussein Nukhailawi.Makki, BS

Eurasia International University, Department of Pharmacy, Yereva, Armenia

*ghazoyanvarduhi@gmail.com

Based on the example of «Furacilin 0,02 % 200 ml solution for external use» drug product the main requirements toward CTD section 3.2.P.8.3 Stability data were extracted and discussed. Section is provided by three main parts: 3.2.P.8.3.1 (Results), 3.2.P.8.3.2 (Analytical procedures and 3.2.P.8.3.3 (Method Validations). Main differences the region specific and ICH general requirements were discussed. Reference sections of CTD, as well as their differences from 3.2.P.8.3 Stability data section were extracted as well. Applicable data according to time zero studies were calculated.

Key-words: Regulation, stability data, Common Technical Document, section 3.2.P.8.3, reference sections.